Pharmacist Naloxone FAQ/Guidance

In 2016, the Missouri General Assembly passed HB 1568 which authorizes Missouri licensed pharmacists to sell and dispense an "emergency opioid antagonist" without a prescription under protocol with an authorizing physician. The new law is effective on August 28, 2016. This Guidance provides general compliance information on the new provisions.

(This Guidance does not include a comprehensive review of HB 1568. Licensees should independently review the legislation to ensure compliance. Copies of HB 1568 are available on the Board's website)

Naloxone Dispensing Without A Prescription

HB 1568 was passed which authorizes Missouri licensed pharmacists to sell and dispense an "emergency opioid antagonist" without a prescription under protocol with an authorizing physician. An "emergency opioid antagonist" is defined as:

Naloxone hydrochloride that blocks the effects of an opioid overdose that is administered in a manner approved by the United States Food and Drug Administration or any accepted medical practice method of administering.

Who Can Dispense/Sell Naloxone?

Under the new law, any Missouri licensed pharmacist may sell and dispense naloxone pursuant to a protocol with a licensed physician. No additional Board license or certification is required.

What has to be included in a protocol?

The Board is in the process of reviewing applicable protocol standards. In the interim, the Board suggests that naloxone protocols include provisions/requirements for:

- · Pharmacist education and training
- · Emergency notification and documentation
- · Patient education and counseling, and
- · Protocol review, signatures and timeframe.

A **sample protocol template** is available on the Board's website on the Naloxone Resource page. Licensees should maintain proof of the authorizing physician's licensure in the pharmacy's records.

Who can buy Naloxone?

HB 1568 allows any individual or entity to purchase naloxone from a pharmacist. However, the pharmacist's protocol may include additional restrictions.

First Responder Agencies: Section **190.255**, **RSMo**, was enacted in 2014 which authorizes any licensed drug distributor or pharmacy to sell naloxone to a "qualified first responder agency". A "qualified first responder agency" is defined by statute as "any state or local law enforcement agency, fire department or ambulance service that provides documented training to its staff related to the administration of naloxone in an apparent narcotic or opiate overdose situation." Pharmacists can sell naloxone to a qualified first responder agency without a protocol.

Is There a Dispensing Limit?

HB 1568 does not include dispensing limits. However, the pharmacist's protocol may include additional restrictions.

Documenting Naloxone Sales and Dispensing

Licensees must document all naloxone sales/dispensing. If naloxone is sold by protocol, the pharmacy must have a record of the sale that should include:

- · Transaction date
- · Product name, strength and dosage form; and
- · Quantity; and
- The names of the parties/entities (if known)

Licensees must comply with all prescription recordkeeping requirements if naloxone is dispensed by prescription.

Pharmacist Education

Pharmacists should educate themselves before dispensing or administering naloxone. To assist licensees, the Board has established a **Naloxone Resource page** on its website that contains a variety of free state and federal naloxone resources for pharmacists.

Patient Education

The Board also suggests that pharmacists educate patients on the proper use and administration of naloxone whenever possible. The Board has drafted a patient educational brochure titled: "Opioid Safety and Naloxone: A Guide for Missouri Patients and Caregivers." The free brochure is available on the Board's website. Copies of the brochure can also be requested online at pr.mo.gov/pharmacists-naloxone.asp or by contacting the Board office.

Also available on the Board's website is a free Opioid Overdose Prevention Toolkit published by the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA). The Toolkit includes the following patient and caregiver resources that can be printed and provided to consumers:

- Safety Advice for Patients & Family Members
- Recovering from Opioid Overdose
- Facts for Community Members

Additional Guidance for Drug Distributors

HB 1568 allows "any person or organization acting under a standing order issued by a health care professional who is authorized to prescribe an opioid antagonist" to store naloxone. Missouri drug distributors may sell naloxone to a qualifying person or organization. Licensees should maintain documentation of the required standing order in their records and document the sale/distribution as otherwise required by law.

Questions?

E-mail the Board office at **compliance@pr.mo.gov** or call (573) 751-0091.